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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/701,001 | 05/30/2001 | Mitsuharu Ono | ASAHI-1-PC-1 | 4787 |

466 7590 09/19/2002

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EXAMINER

SAUNDERS, DAVID A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1644

DATE MAILED: 09/19/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

701,001

Applicant(s)

ONO et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-28 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-28 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: Antibodies directed to any of numerous and various specific cellular antigens: e.g. various CD antigens, ICAMs, tumor associated antigens, histocompatibility antigens, etc.

Applicant is required, in reply to this action, to elect a single species (a method using an antibody to a particular cellular antigen) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 2-4 and 11-13 for methods involving CD4+ cell separation.

Claims 5-7 and 14-16 for methods involving CD34+ cell separation.

The following claim(s) are generic: 1, 8-10, and 17.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The IPEA has found prior art against claims 1-2, 5, 8-11, 14 and 17. PCT Rule 13.2 requires that the special technical features pertaining to an invention

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having unity define a contribution over the prior art. Since the IPEA has found prior art, applicant's claims define no contribution over the prior art, and requiring an election of species is proper.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 8-9, drawn to devices for cell separation.

Group II, claim(s) 2-4, drawn to devices for CD4+ cell separation.

Group III, claim(s) 5-7, drawn to devices for CD34+ cell separation.

Group IV, claim(s) 10 and 17, drawn to methods for cell separation and detection.

Group V, claim(s) 11-13, drawn to methods for CD4+ cell separation and detection.

Group VI, claim(s) 14-16, drawn to methods for CD34+ cell separation and detection.

Group VII, claim(s) 18-20 and 24-28, drawn to antibodies to CD4 antigen.

Group VIII, claim(s) 21-23, drawn to nucleic acids encoding antibodies to CD4 antigen and methods of antibody production.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The IPEA has found prior art against claims 1-2, 5, 8-11, 14 and 17. PCT Rule 13.2 requires that the special technical features pertaining to an invention having unity define a contribution over the prior art. Since the IPEA has found prior art, applicant's claims define no contribution over the prior art, and restriction is proper in accord with U.S. practice.

It is noted that the methods of Groups II (and IV) versus III (and VI) each involve the use of antibodies to different and distinct antigens. The searches for each of these involve searches for different and distinct amino acid sequences.

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The separation or detection methods of Groups IV-VI do not use a cell separation device as do the separation methods of Groups I-III. Therefore Groups IV-VI are properly separated from Groups I-III.

The antibodies of Group VII could be used in methods other than the separation/detection methods of Groups II and V. For example antibodies can be used to affinity purify isolated antigens; also antibodies can be used to make anti-idiotypic antibodies.

The antibody and nucleic acid products of Groups VII and VIII have different structures and functions. Searches for these involve different sequence searches.

In the event that applicant elects one of Groups II or III, the antibody specificity of the elected Group will be examined as the elected antibody specificity of Group I. In the event that applicant elects one of Groups V or VI, the antibody specificity of the elected Group will be examined as the elected antibody specificity of Group IV.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976. The examiner can normally be reached on Mon.-Thu., 8:00 am-5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax number for a response to a restriction requirement for the organization where this application is assigned is 703-305-3704; use attached form.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAS
September 18, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/644



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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